

PATENT
454313-2541.2

AMENDMENT

Kindly amend the application, without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents as follows.

IN THE CLAIMS:

Kindly amend the claims, without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents, to read as follows:

1. (Currently Amended) A combined immunological, immunogenic or vaccine composition ~~comprising~~ consisting essentially of a first antigen or epitope of interest from a first enteric pathogen comprising *Cryptosporidium* and/or a first vector that expresses the first antigen or epitope of interest, and a second antigen or epitope of interest from a second enteric pathogen and/or the first vector that expresses the first antigen or epitope of interest also expresses the second antigen or epitope of interest and/or a second vector that expresses the second antigen or epitope of interest, and a pharmaceutically acceptable vehicle wherein the first and second enteric pathogens can be the same enteric pathogen or different enteric pathogens.
2. (Currently Amended) The composition according to claim 1 ~~comprising~~ consisting essentially of an antigen from *Cryptosporidium parvum* and an antigen from a second enteric pathogen.
3. (Currently Amended) The composition according to claim 2 ~~comprising~~ consisting essentially of an antigen from *Cryptosporidium* and an antigen from a second enteric pathogen wherein the second enteric pathogen is a pathogen of a bovine species.
4. (Withdrawn) The composition according to claim 2 comprising an antigen from *Cryptosporidium* and an antigen from an enteric pathogen of a canine species.
5. (Withdrawn) The composition according to claim 2 comprising an antigen from *Cryptosporidium* and an antigen from an enteric pathogen of a feline species.

PATENT
454313-2541.2

6. (Withdrawn) The composition according to claim 2 comprising an antigen from *Cryptosporidium* and an antigen from an enteric pathogen of an equine species.
7. (Withdrawn) The composition according to claim 1, wherein the antigen from the enteric pathogen is selected from the group consisting of the antigens from *E. coli*, rotavirus, coronavirus, *Clostridium spp.* and mixtures thereof.
8. (Withdrawn) The composition according to claim 1, wherein the enteric pathogen comprises *E. coli*.
9. (Withdrawn) The composition according to claim 8, wherein the antigen from *E. coli* comprises an antigen selected from the group consisting of inactivated *E. coli* bearing K99 antigen, inactivated *E. coli* bearing F41 antigen, inactivated *E. coli* bearing Y antigen, inactivated *E. coli* bearing 31A antigen, K99 antigen, F41 antigen, Y antigen, 31A antigen, and mixtures thereof.
10. (Withdrawn) The composition according to claim 9 wherein the *E. coli* antigen comprises a K99 antigen selected from the group consisting of inactivated *E. coli* bearing the K99 antigen, K99 antigen, and mixtures thereof; and/or a F41 antigen selected from the group consisting of inactivated *E. coli* bearing the F41 antigen, F41 antigen, and mixtures thereof.
11. (Withdrawn) The composition according to claims 3, wherein the enteric pathogen comprises bovine coronavirus.
12. (Withdrawn) The composition according to claim 3, wherein the enteric pathogen comprises bovine rotavirus.
13. (Withdrawn) The composition according to claim 3, wherein the enteric pathogen comprises *Clostridium perfringens*.

PATENT
454313-2541.2

14. (Withdrawn) The composition according to claim 13, wherein the antigen of the enteric pathogen comprises *Clostridium perfringens* type C and/or D toxoids.

15. (Withdrawn) The composition according to claim 3, wherein the enteric pathogen comprises *E. coli*, bovine rotavirus, bovine coronavirus and *Clostridium perfringens* or *E. coli*, bovine rotavirus, bovine coronavirus.

16. (Withdrawn) The composition according to claim 15, wherein the antigen of the enteric pathogen comprises *E. coli* antigens selected from the group consisting of inactivated *E. coli* bearing K99 antigen, inactivated *E. coli* bearing F41 antigen, inactivated *E. coli* bearing Y antigen, inactivated *E. coli* bearing 31A antigen, K99 antigen, F41 antigen, Y antigen, 31A antigen, and mixtures thereof; inactivated bovine coronavirus; inactivated bovine rotavirus and *Clostridium perfringens* type C and/or D toxoids; or *E. coli* antigens selected from the group consisting of inactivated *E. coli* bearing K99 antigen, inactivated *E. coli* bearing F41 antigen, inactivated *E. coli* bearing Y antigen, inactivated *E. coli* bearing 31A antigen, K99 antigen, F41 antigen, Y antigen, 31A antigen and mixtures thereof; inactivated bovine coronavirus; and inactivated bovine rotavirus.

17. (Withdrawn) The composition according to claim 16 wherein the *E. coli* antigen comprises a K99 antigen selected from the group consisting of inactivated *E. coli* bearing the K99 antigen, K99 antigen, and mixtures thereof; and/or a F41 antigen selected from the group consisting of inactivated *E. coli* bearing the F41 antigen, F41 antigen, and mixtures thereof.

18. (Currently Amended) The composition according to claim 3, comprising consisting essentially of sub-unit *Cryptosporidium parvum* antigens selected from the group consisting of P21, Cp23, Cp15/60, CP41 and mixtures thereof.

19. (Withdrawn) The composition according to claim 15, comprising sub-unit *Cryptosporidium parvum* antigens selected from the group consisting of P21, Cp23, Cp15/60, CP41 and mixtures thereof.

PATENT
454313-2541.2

20. (Withdrawn) The composition according to claim 16, comprising sub-unit *Cryptosporidium parvum* antigens selected from the group consisting of P21, Cp23, Cp15/60, CP41 and mixtures thereof.
21. (Currently Amended) The composition according to claim 18, ~~comprising~~ consisting essentially of Cp23 and Cp15/60.
22. (Withdrawn) The composition according to claim 19, comprising Cp23 and Cp15/60.
23. (Withdrawn) The composition according to claim 20, comprising Cp23 and Cp15/60.
24. (Currently Amended) The composition according to claim 18, ~~comprising~~ consisting essentially of P21 and Cp15/60.
25. (Currently Amended) The composition according to claim 1, which further ~~comprises~~ consists essentially of an adjuvant.
26. (Withdrawn) The composition according to claim 15, which further comprises an adjuvant.
27. (Withdrawn) The composition according to claim 26, wherein the adjuvant comprises saponin.
28. (Withdrawn) The composition according to claim 26, wherein the adjuvant comprises aluminum hydroxyde.
29. (Withdrawn) The composition according to claim 26, wherein the composition is in the form of an oil-in-water emulsion.
30. (Currently Amended) An immunological, immunogenic or vaccine composition against *Cryptosporidium parvum*, which ~~comprises~~ consists essentially of a first antigen comprising a

PATENT
454313-2541.2

P21 or Cp23 antigen or an epitope thereof or a first vector that expresses the first antigen and a second antigen comprising Cp15/60 antigen or epitope thereof or the first vector wherein the first vector expresses both the first and second antigens or a second vector that expresses the second antigen, and a pharmaceutically acceptable vehicle.

31. (Original) The composition according to claim 30, wherein P21 or Cp23 and Cp15/60 antigens are in the form of separate fusion proteins.

32. (Withdrawn) The composition according to claim 30, which comprises a vector expressing P21 and Cp15/60.

33. (Withdrawn) The composition according to claim 30, which comprises a recombinant vector expressing P21 and a recombinant vector expressing Cp15/60.

34. (Currently Amended) The composition according to claim 30, which ~~comprises~~ consists essentially of Cp23 and Cp15/60.

35. (Currently Amended) The composition according to claim 30, which further ~~comprises~~ consists essentially of an adjuvant.

36. (Currently Amended) An immunological, immunogenic or vaccine composition against *Cryptosporidium parvum*, which ~~comprises~~ consists essentially of a first antigen comprising a P21 or Cp23 or Cp15/60 or CP41 antigen or an epitope thereof or a first vector that expresses the first antigen and a second antigen comprising a second antigen or epitope thereof from *Cryptosporidium parvum* or the first vector wherein the first vector expresses both the first and second antigens or a second vector that expresses the second antigen, wherein the first and second antigens are different from each other, and a pharmaceutically acceptable vehicle.

37. (Withdrawn) A method of bovine immunization of a new-born calf against enteric disease comprising administering the composition according to claim 1 to a pregnant cow before calving, so that the new-born calf has maternal antibodies against *Cryptosporidium parvum*.

PATENT
454313-2541.2

38. (Withdrawn) The method according to claim 37, which comprises further the feeding to the newborn calf colostrum and/or milk from the cow which has been administered the composition during pregnancy.
39. (Withdrawn) A method of active immunization of adult and new-born bovines, comprising administering to the bovines a composition as claimed in claim 1.
40. (Withdrawn) The method of claim 37 further comprising administering the composition to the new-born calf.
41. (Withdrawn) The method of claim 38 further comprising administering the composition to the new-born calf.
42. (Withdrawn) The method of claim 40 wherein the composition administered to the cow comprises antigens or epitopes thereof and the composition administered to the calf comprises vectors.
43. (Withdrawn) The method of claim 41 wherein the composition administered to the cow comprises antigens or epitopes thereof and the composition administered to the calf comprises vectors.
44. (Withdrawn) A method for preparing a composition according to claim 1 comprising admixing the antigens or epitopes or vectors and the carrier.
45. (Currently Amended) A kit for preparing a composition according to claim 1 ~~comprising~~ consisting essentially of the antigens, epitopes or vectors each in separate container or containers, optionally packaged together; and further optionally with instructions for admixture and/or administration.

PATENT
454313-2541.2

46. (Withdrawn) A hyperimmunized colostrum and/or milk composition obtained by administering a composition according to claim 1 to a pregnant cow and thereafter removing colostrum and/or milk from the cow.
47. (Withdrawn) The composition of claim 46 wherein the composition comprises concentrated immunoglobulins obtained by coagulation of the colostrum and/or milk and recovery of immunoglobulins.
48. (Withdrawn) A method for preventing, treating and/or controlling enteric disease, symptom(s) and/or condition(s) and/or pathogen(s) responsible for such disease, symptom(s) and/or condition(s) and/or *C. parvum* comprising administering to a new-born calf the composition of claim 46.
49. (Withdrawn) A method for preventing, treating and/or controlling enteric disease, symptom(s) and/or condition(s) and/or pathogen(s) responsible for such disease, symptom(s) and/or condition(s) and/or *C. parvum* comprising administering to a new-born calf the composition of claim 47.
50. (Withdrawn) The method of claim 48 wherein the administering is oral administration.
51. (Withdrawn) The method of claim 49 wherein the administering is oral administration.
52. (Withdrawn) The method of claim 50 wherein the oral administration is by the new-born calf nursing from the cow.
53. (Withdrawn) A method for preparing a hyperimmunized colostrum and/or milk composition comprising administering a composition according to claim 1 to a pregnant cow and thereafter removing colostrum and/or milk from the cow.
54. (Withdrawn) The method of claim 53 further comprising concentrating immunoglobulins in the milk and/or colostrum obtained from the cow by coagulation of the

PATENT
454313-2541.2

colostrum and/or milk and recovery of immunoglobulins, whereby the composition comprises said immunoglobulins.

55. (Withdrawn) A method of using a first antigen or epitope from *Cryptosporidium* and/or a vector that expresses such antigen or epitope, and a second antigen or epitope from a second enteric pathogen and/or a vector that expresses such antigen or epitope, for the preparation of an immunogenic or vaccine composition against enteric infections, comprising admixing the first antigen or epitope and/or vector and the second antigen or epitope and/or vector.

56. (Currently Amended) An immunological, immunogenic or vaccine composition against *Cryptosporidium parvum*, which ~~comprises~~ consists essentially of a first antigen comprising a P21 antigen or an epitope thereof and a second antigen comprising Cp15/60 antigen or epitope thereof, and a pharmaceutically acceptable vehicle.